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Examiner Name	R. Smith
Attorney Docket Number	780-A03-040-8

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): P. Bonutti

Application No.: 10/666,101

Filed: September 18, 2003

For: MAGNETIC RESONANCE IMAGING SYSTEM AND METHOD (as amended)

Confirmation No.: 7131

Attorney Docket No.: 780-A03-040-8

Group Art Unit: 3737

Examiner: R. Smith

RESPONSE TO OFFICE ACTION

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed July 6, 2004, Applicant hereby submits the following amendments and remarks for the above-identified application. In accordance with USPTO practice, each section of this Response begins on a separate sheet. Reconsideration and allowance of the pending claims in view of the following are respectfully requested.

Amendments to the Specification

Please replace the following paragraphs.

Title of the Invention:

~~APPARATUS AND METHOD FOR USE IN MEDICAL IMAGING~~ MAGNETIC RESONANCE IMAGING SYSTEM AND METHOD

Paragraph [0001]:

This application is a continuation of Application No. 09/118,665, filed July 17, 1998, now U.S. Patent No. 6,697,659. The aforementioned Application No. 09/118,665 is itself a divisional of Application No. 08/455,074, filed May 31, 1995, now U.S. Patent No. 6,671,537. The aforementioned Application No. 08/455,074 is a divisional of Application No. 08/221,848, filed April 1, 1994, now U.S. Patent No. 5,577,503. The aforementioned Application No. 08/221,848 is itself a divisional of Application No. 07/802,358, filed December 4, 1991, now U.S. Patent No. 5,349,956.

Amendments to the Claims

1. (currently amended) A magnetic resonance imaging system comprising:

a stationary electromagnet;

a patient support located adjacent to the electromagnet, the support configured for maintaining a patient in a standing position; and

an actuator for raising and lowering the patient support and patient relative to a magnetic field of the electromagnet such that the patient is located within the magnetic field.

2. (original) A magnetic resonance imaging system as defined in claim 1 further including at least one positioning fixture connected with the patient support for maintaining the patient in the standing position.

3. (currently amended) A magnetic resonance imaging system as defined in claim 2 further including at least one secondary coil ~~electromagnet~~ positioned within the magnetic field of the stationary electromagnet.

4. (currently amended) A magnetic resonance imaging system comprising:

a stationary electromagnet having a longitudinal axis extending generally vertical;

a patient support located adjacent to the electromagnet for maintaining a patient in a seated position; and

an actuator for raising and lowering ~~lowing~~ the patient support and patient relative to a magnetic field of the electromagnet such that the patient is located within the magnetic field.

5. (original) A magnetic resonance imaging system as defined in claim 4 further including at least one positioning fixture connected with the patient support for maintaining the patient in the seated position.

6. (currently amended) A magnetic resonance imaging system as defined in claim 5 further including at least one secondary coil ~~electromagnet~~ positioned within the magnetic field of the stationary electromagnet.

7. (currently amended) An apparatus for magnetic resonance imaging of a joint of a patient, the apparatus comprising:

a stationary electromagnet;

a patient support located adjacent to the electromagnet, the support configured for maintaining a patient in a standing position;

at least one positioning fixture connected with the patient support for holding the joint of the patient; and

an actuator for raising and lowering the patient support and patient relative to a magnetic field of the electromagnet such that the joint of the patient is located within the magnetic field.

8. (currently amended) An apparatus as defined in claim 7 further including means for applying a first force to the joint ~~wherein the joint is subjected to a first force~~.

9. (currently amended) An apparatus as defined in claim 7 further including means for applying a second force to the joint, wherein the ~~joint is subjected to a~~ second force ~~which~~ is greater than the first force.

10. (currently amended) An apparatus for magnetic resonance imaging of a joint of a patient, the apparatus comprising:

a stationary electromagnet having a longitudinal axis extending generally vertical;

a patient support located adjacent to the electromagnet for maintaining a patient in a seated position;

at least one positioning fixture connected with the patient support for holding the joint of the patient; and

an actuator for raising and lowering the patient support and patient relative to a magnetic field of the electromagnet such that the joint of the patient is located within the magnetic field.

11. (currently amended) An apparatus as defined in claim 10 further including means for applying a first force to the joint ~~wherein the joint is subjected to a first force~~.

12. (currently amended) An apparatus as defined in claim 10 further including means for applying a second force to the joint, wherein the ~~joint is subjected to a~~ second force ~~which~~ is greater than the first force.

13. (currently amended) An apparatus for magnetic resonance imaging of a spine of a patient, the apparatus comprising:

a stationary electromagnet;

a patient support located adjacent to the electromagnet, the support configured for maintaining a patient in a standing position;

at least one positioning fixture connected with the patient support for holding the spine of the patient; and

an actuator for raising and lowering the patient support and patient relative to a magnetic field of the electromagnet such that the spine of the patient is located within the magnetic field.

14. (currently amended) An apparatus as defined in claim 13 further including means for applying a first force to the spine ~~wherein the spine is subjected to a first force~~.

15. (currently amended) An apparatus as defined in claim 13 further including means for applying a second force to the spine, wherein the ~~spine is subjected to a~~ second force ~~which~~ is greater than the first force.

16. (currently amended) An apparatus for magnetic resonance imaging of a spine of a patient, the apparatus comprising:

a stationary electromagnet having a longitudinal axis extending generally vertical;

a patient support located adjacent to the electromagnet for maintaining a patient in a seated position;

at least one positioning fixture connected with the patient support for holding the spine of the patient; and

an actuator for raising and lowering the patient support and patient relative to a magnetic field of the electromagnet such that the spine of the patient is located within the magnetic field.

17. (currently amended) An apparatus as defined in claim 16 further including means for applying a first force to the spine ~~wherein the spine is subjected to a first force~~.

18. (currently amended) An apparatus as defined in claim 16 further including means for applying a second force to the spine, wherein the ~~spine is subjected to a~~ second force ~~which~~ is greater than the first force.

19. (currently amended) A method for magnetic resonance imaging, the method comprising the steps of:

positioning a patient against a patient support configured for maintaining the patient ~~such that the patient is maintained~~ in a standing position;

moving the patient into a magnetic field of a stationary electromagnet; and

imaging the patient with the electromagnet.

20. (original) A method as defined in claim 19 further including the step of using at least one positioning fixture to maintain the patient in a generally fixed position before imaging the patient with the electromagnet.

21. (currently amended) A method as defined in claim 19 wherein the step of imaging the patient with the electromagnet includes imaging the patient with the stationary electromagnet and a secondary coil ~~electromagnets~~.

22. (currently amended) A method for magnetic resonance imaging, the method comprising the steps of:

positioning a patient against a patient support such that the patient is maintained in a seated position;

moving the patient into a magnetic field of a stationary electromagnet having a longitudinal axis extending generally vertical; and[[,]]

imaging the patient with the electromagnet.

23. (original) A method as defined in claim 22 further including the step of using at least one positioning fixture to maintain the patient in a generally fixed position before imaging the patient with the electromagnet.

24. (currently amended) A method as defined in claim 22 wherein the step of imaging the patient with the electromagnet includes imaging the patient with the stationary electromagnet and a secondary coil ~~electromagnets~~.

Remarks

Claims 1-24 remain in this application and are presented for the Examiner's review and consideration. In this Response, Applicant has amended claims 1, 3, 4, 6-19, 21, 22, and 24. Applicant believes the amendments and remarks herein serve to place this application in better condition for allowance and are independent of patentability.

Specification Objections

The disclosure was objected to because of the following informalities: on page 1 the status of continuing data requires updating and the title of the invention is not descriptive. In response, Applicant has corrected these informalities.

Claim Objections

Claim 4 was objected to for a misspelling. The misspelling has been corrected. Claims 8, 9, 11, 12, 14, 15, 17, and 18 were objected to "because it is unclear as to what further structural limitations have been set forth." In response, Applicant has amended these claims to address the objection. Applicant submits that these amendments are supported at least by paragraph [0133] of the specification.

35 U.S.C. §112 Rejections

Claims 3, 6, 21, and 24 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner stated:

> the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time of the application was filed, had possession of the claimed invention. The specification fails to disclose that the system includes a secondary electromagnet.

In response, Applicant has amended claims 3, 6, 21, and 24 to include, *inter alia*, a secondary coil. Applicant submits that a secondary coil is described throughout the specification.

Ordinary Engineering Design Choice

Claims 1, 2, 4, 5, 7-20, 22, and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Damadian in view of Matsutani (and Shah, for some claims). In citing

Damadian, the Examiner posits that a patient seated within the imaging chamber (see FIG. 1) is positioned in a vertical orientation. The Examiner further states that "if a small child [were] being imaged the system would be capable of imaging a patient in a seated or standing position. In the absence of any showing of unexpected results, whether the patient is seated or standing, as long as they are oriented vertically, would have been a matter of ordinary engineering design choice." In response, Applicant respectfully contests the Examiner's position.

As an initial matter, Applicant objects to the Examiner's statement, "...whether the patient is seated or standing, as long as they are oriented vertically..." In this statement, the Examiner as labeled the seated and standing positions as vertical positions. Applicant, on the other hand, uses the term "vertical position" to describe the standing position. As stated in the specification, a patient may be placed in a standing or seated position. (paragraph [0132]). With the patient in a vertical or in a seated position, it is possible to simulate joint positionings and joint loadings. For example, the knee can be imaged with the patient standing. (paragraph [0133]). Therefore, Applicant contends that the specification uses the terms "standing position" and "vertical position" interchangeably and uses the term "seated position" to define the seated position. Accordingly, Damadian does not disclose a patient being imaged in a vertical (or standing) position.

Moreover, the rationale of "obvious matter of design choice" applies when a modification is made which "solves no stated problem." *In re Kuhle*, 188 USPQ 7, 9 (CCPA 1975). Applicant respectfully submits that the present invention solves a stated problem. Specifically, when a patient is in a standing (or vertical) position, it is possible to simulate joint positionings and joint loadings which can not readily be simulated when the patient is lying down. For example, the knee can be imaged with the patient standing to see how the joint appears when loaded with body weight. Also, with the patient standing, the spine can be imaged to check for disc or vertebral problems. (paragraph [0133]). (Applicant further asserts that while a patient's spine may be scanned with the patient seated, the spine is subjected to different forces when the patient is standing thereby providing a different image of the spine.)

Damadian, on the other hand, does not state or solve the problem of imaging a patient loaded with body weight and/or a heavy object. Applicant contends that nowhere in his disclosure does Damadian discuss the need to image a patient loaded with body weight or the advantages thereof. Instead, Damadian states that the present invention is particularly useful in

cancer detection or whenever diseased tissue is chemically different from normal tissue. (col. 2, lines 27-31). Furthermore, although Damadian shows a patient in a seated position in FIG. 1, Damadian states that "it is preferred that the human patient be positioned to lie on his back, since the length of the pencil beam provided by transmitter coils 60 and 62 which extends through the specimen is minimized." (col. 9, lines 20-23). Therefore, Damadian's orientation of the patient is not driven by the need to image the patient subjected to forces. Rather, Damadian's patient orientation preference is driven by the need to minimize equipment requirements.

In addition to solving a stated problem, Applicant's invention is counterintuitive to one of ordinary skill in the art. Specifically, it is counterintuitive to perform magnetic resonance imaging of a patient in a standing orientation.

To obtain a cross sectional scan of a patient, Damadian uses a doughnut shaped magnet 30 preferably superconducting. (col. 3, lines 14-16). The primary static magnetic field configuration within the doughnut shaped magnet 30 alone is well known in the art. (col. 3, lines 37-39). As illustrated in FIG. 1, the chamber within the doughnut shaped magnet 30 is sized to accommodate a patient in a seated orientation. As stated in U.S. Patent No. 4,875,485 to Matsutani ("Matsutani") cited by the Examiner, a magnet for a magnetic resonance system is required to be quite large, and, for example, in the case of a superconducting magnet, the magnet is 2.4 m in length, 2 m in width, 2.4 m in height and 5 to 6 tons by weight (col. 1, lines 65-68). The chamber of such a superconducting magnet is in the form of a large 40-50 cm sphere. (col. 1, lines 62-63). For a patient to be seated within the chamber of Damadian's superconducting magnet, the magnet would need to be at least as large as Matsutani's magnet. Applicant posits that a 5 to 6 ton imaging magnet would require excessive logistics to manufacture, ship, and install. Also, the imaging room would need to be structurally capable of accommodating such a large and heavy magnet. Therefore, to design, manufacture, and install a larger and heavier magnet for imaging a patient in a standing orientation would have been counterintuitive to designing imaging magnets. In fact, as stated above, Damadian preferred to orient the patient in a prone position to minimize equipment requirements. A superconducting magnet capable of accommodating a standing patient would defeat Damadian's goal of using smaller imaging equipment.

Based on the foregoing, Applicant respectfully submits that imaging a patient in a standing position would not have been a matter of ordinary engineering design choice. As such,

Applicant contends that Damadian does not teach or suggest imaging a patient in a standing orientation. Therefore, with respect to claims 1, 2, 4, 5, 7-20, 22, and 23, Applicant submits that Damadian does not teach or suggest all the claim limitations and, as a result, the §103(a) rejections should be withdrawn. Applicant further submits that Matsutani and Shah fail to remedy the deficiencies of Damadian.

35 U.S.C. §103 Rejections

Claims 1, 4, 19, and 22 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,411,270 to Damadian ("Damadian") in view of U.S. Patent No. 4,875,485 to Matsutani ("Matsutani"). Specifically, the Examiner stated:

> Damadian discloses a method and apparatus for providing magnetic resonance imaging wherein the patient is positioned in a vertical orientation. If a small child [were] being imaged the system would be capable of imaging a patient in a seated or standing position. In the absence of any showing of unexpected results, whether the patient is seated or standing, as long as they are oriented vertically, would have been a matter of ordinary engineering design choice. Damadian discloses that in addition to moving the patient, one can instead move the imaging volume 44. Matsutani discloses a MRI system with means for positioning the patient such that a desired portion of the patient is imaged. Such means includes an actuator for raising or lowering the patient support to properly position the patient. It would have been obvious to one skilled in the art to have modified Damadian such that it includes an actuator for raising and lowering the patient in order to properly position the patient such that the imaging volume is placed within a desired body portion.

Also, claims 2, 5, 7-18, 20, and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Damadian in view of Matsutani and U.S. Patent No. 5,154,178 to Shah ("Shah"). Specifically, the Examiner stated:

> Shah discloses an MRI system which includes the use of a positioning fixture to maintain the patient in a fixed position during imaging. It would have been obvious to one skilled in the art to have further modified Damadian such that it includes a positioning fixture to maintain the patient in a fixed position during imaging. The advantage of such is to ensure proper placement of patient during imaging...With respect to claims 8, 9, 11, 12, 14, 15, 17, 28, there are inherently forces that the body is subjected to and the forces of gravity will be greater than the upward forces applied by the support. It should be noted that the system of Damadian can be applied to image any body portion.

In response, Applicant respectfully submits that these rejections should be withdrawn.

Damadian discloses an apparatus and method for nuclear magnetic resonance scanning and mapping. The apparatus is used to analyze the chemical structure of a cross section of a live specimen. (col. 3, lines 12-13). In FIG. 1, a human is shown in a sitting position with the coil 46 positioned to surround the chest. (col. 4, lines 47-49). Scanning of a cross section of the specimen 32 in the embodiment shown in FIG. 1 is accomplished by using a translator beam 48 on which the specimen 32 is placed. Drive box 49 includes motors and gears for moving the translator beam 48 in a conventional manner in the "X" direction and "Z" direction. The drive box 49 is automatically activated by control unit 52 in a conventional manner to move the specimen 32 with respect to the stationary resonance domain 44 in a grid pattern in a "X-Z" plane through the specimen 32. (col. 5, lines 56-66).

In a particular configuration shown in FIG. 8, it is preferred that the human patient be positioned to lie on his back, since the length of the pencil beam provided by transmitter coils 60 and 62 which extends through the specimen is minimized. (col. 9, lines 21-24). As shown in FIG. 8, the pencil scanning beam provided by transmitter coils 60 and 62 is along "Y" axis. The beam and specimen are moved incrementally along the "X" axis by a conventional drive box 48a and drive control unit 50a after a complete scan along the pencil beam along the "Y" axis is completed. (col. 8, lines 49-54).

Matsutani discloses a magnetic resonance system which includes a magnet that generates a static field; a bed that holds a body to be examined by placing the body thereon, within the static field; and a drive apparatus that is connected to either the magnet or the bed, and varies a positional relationship between the magnet and the bed. (col. 3, lines 14-23). To the bed or platform 2 is attached a platform up/down drive unit 30. The device unit 30 is operated, for example, by hydraulic means. (col. 4, lines 61-63). The platform 2 is raised to a position suitable for a technician to readily perform necessary procedures. (col. 6, lines 31-32).

Shah discloses a nuclear magnetic resonance examination apparatus comprising support means 10 which is attachable to a subject adjacent to a joint to be examined using either magnetic resonance imaging or magnetic resonance spectroscopy techniques. (col. 3, lines 10-14). Support means 10 includes base member 18 for the support of first and second relatively movable support members 20 and 22, the upper faces of which are at the same level above base member 18. (col. 3, lines 19-22).

In contrast, Applicant discloses an apparatus and method for imaging a body part with an

MRI coil. The primary MRI coil 368 extends vertically rather than horizontally. A patient may be placed in a standing or seated position on a support 370 for imaging in the coil 368. A ram 272 is operable to move the patient into and out of the coil 368. Positioning fixtures, etc. are mounted to a support member 374. (paragraph [0132]). With the patient in a vertical or in a seated position, it is possible to simulate joint positionings and joint loadings which can not readily be simulated when the patient is lying down in a known horizontal imaging coil. For example, weight or other tractive force can be attached to the arm to simulate shoulder joint loading experienced when carrying a heavy object. The knee can be imaged with the patient standing to see how the joint appears when loaded with body weight. The spine can be imaged when standing or seated to check for disc or vertebral problems which are experienced in normal life but which disappear when the patient lies down to be imaged in a known horizontal imaging coil. (paragraph [0133]).

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143.

Applicant respectfully contends that there is no suggestion or motivation to combine Damadian and Matsutani. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984). Damadian uses a drive box for moving the patient with respect to the stationary resonance domain in a grid pattern in a "X-Z" plane through the patient. As seen in FIG. 1, the "X-Z" plane of Damadian is a horizontal plane. Furthermore, as seen in FIG. 8, the patient is moved incrementally along the "X" axis by a conventional drive box. Therefore, scanning the patient is achieved by moving the patient along a horizontal plane. Meanwhile, Matsutani teaches the use of a bed or platform having an up/down drive unit. The patient lies down on the bed in a prone position, and the drive unit is used to raise and lower the patient.

Applicant respectfully submits that modifying Damadian's scanning device with Matsutani's drive unit would render Damadian's scanning system unsatisfactory for its intended

purpose. In order to obtain a cross sectional scan of the patient, Damadian moves the patient horizontally while maintaining the patient in a fixed position relative to the vertical axis. Applying Matsutani's up/down drive unit to Damadian's scanning system would distort or break-up the desired cross sectional image, rendering the image unsatisfactory and unusable for analyzing the chemical structure of a specimen.

Secondly, there must be a reasonable expectation of success to establish a prima facie case of obviousness. Applicant respectfully contends that the combination of Damadian and Matsutani would have no reasonable expectation of success. The cross sectional scan produced by Damadian's device requires the patient to be stationary along the vertical axis. A complete, uninterrupted scan of a cross section of a patient is used by physicians to determine the chemical and structural composition of the patient. Any movement along the vertical axis during scanning would generate an incomplete and unsatisfactory image for patient evaluation. Consequently, no expectation of success is achieved when combining Matsutani's up/down drive unit with Damadian's scanning system.

Finally, Applicant respectfully submits that the prior art references, when combined, do not teach or suggest all the claim limitations. Applicant discloses a patient support for placing the patient thereon in a standing position. (paragraph [0132]). That is, the patient support is configured to support the patient's feet. In contrast, the patient supports of Damadian (FIG. 1 and 8) and Matsutani (FIG. 1) are configured for supporting the patient's dorsal side. To highlight this distinction, Applicant has amended independent claims 1, 7, 13, and 19 to include, *inter alia*, a patient support configured for supporting the patient in a standing position. Additionally, Applicant teaches a stationary electromagnet that extends vertically. (paragraph [0132] and FIG. 43). In contrast, Damadian discloses a stationary electromagnet that extends horizontally. (FIGS. 1-14B). Matsutani discloses movable electromagnets (Helmholtz magnets) that are attached to magnet supports and drive units. To highlight these distinctions, Applicant has amended independent claims 4, 10, 16, and 22 to include, *inter alia*, a stationary electromagnet having a longitudinal axis extending generally vertical.

In sum, with respect to claims 1, 2, 4, 5, 7-20, 22, and 23, Applicant respectfully contends that the Examiner has not established a prima facie case of obviousness because there is no motivation or suggestion to combine the teachings of Damadian and Matsutani, there is no reasonable expectation of success in combining the references, and the cited references fail to

teach or suggest all the claim limitations of the amended independent claims. Regarding claims 2, 5, 7-18, 20, and 23, Applicant contends that Shah fails to remedy the lack of a prima facie case of obviousness when combined with Damadian and Matsutani.

Conclusion

In light of the foregoing amendments and remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

The $180.00 fee set forth in 37 C.F.R. §1.17 (p) in accordance with 37 C.F.R. §1.97 (c) is being paid via enclosed Credit Card Payment form. Please charge (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601. (Attorney Docket No. 780-A03-040-8)

Respectfully submitted,

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